

510K Summary

Date: August 27, 2011

Submitter: Zavation LLC
501 Avalon Way
Brandon, MS 39047
Phone: 601-919-1119
Fax: 800-447-1302

Contact person: John Walker

Type of 510(k) submission: Traditional

Trade name: Zavation Spinal System

Common name: Spinal Fixation System

Classification regulation: 888.3070 (MNH, MNI)
888.3060 (KWQ)

Device classification: Class II

Classification Panel: Orthopedic

Product code: MNH, MNI, KWQ

Basis for submission: New device

Device Description: The Zavation Spinal System is comprised of polyaxial pedicle screws, rods and crosslinks. The Zavation Spinal System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors.

Intended Use: The Zavation Spinal System is a pedicle screw system intended to provide Immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Zavation Spinal Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Zavation Spinal Systems when used as anterior thoracic/lumbar screw fixation systems, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

Materials:

The Zavation Spinal System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Device:

Depuy Spine Moss Miami Spine System (K955348)

Depuy Spine Expedium Spine System (K033901)

Technological Characteristics:

The Zavation Spinal System possesses the same technological characteristics as the predicate devices. These include: basic design (rod based fixation system having polyaxial pedicle screws with various screw and rod diameters and lengths), material (titanium alloy), mechanical safety and performances, and intended use (as described above).

Performance Data:

Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case construct. The mechanical test results demonstrated that the Zavation Spinal System performs as well as or better than the predicate devices.

Conclusion:

The Zavation Spinal System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

NOV 22 2011

Zavation LLC
% Mr. John Walker
Engineering Manager
501 Avalon Way
Brandon, Mississippi 39047

Re: K112484

Trade/Device Name: Zavation Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: October 06, 2011
Received: October 14, 2011

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K112484

Indications for Use

510(k) Number: K112484

Device Name: Zavation Spinal System

Indications For Use:

The Zavation Spinal System is a pedicle screw system intended to provide Immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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